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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/321,247	05/27/1999	SI-YI CHEN	0443-2U2	6190

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EXAMINER
LOEB, BRONWEN

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/321,247	CHEN ET AL.	
	Examiner	Art Unit	
	Bronwen M. Loeb	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24,29 and 33-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,29 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This action is in response to the amendment filed 29 October 2002 in which claims 1, 17, 19, 29 and 35 were amended.

Claims 1-24, 29 and 33-39 are pending.

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specification

2. The disclosure is objected to because of the following informalities: SDF is stated to be a CXC chemokine (p. 11, line 9) and to bind to CXR4 (p. 11, lines 11-13). It is subsequently stated that SDF binds to CCR4 (p. 11, line 26). Is this latter statement a typographical error?

Appropriate correction is required.

Claim Objections

3. Applicant is advised that should claim 1 be found allowable, claims 35-37 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 35 recites an intended use for an expression vector; the structural elements of the expression vector are identical to those in claim 1. An intended use recitation does not provide patentable distinction to a claim unless it results in a structural difference.

Response to Amendment

4. The rejection of claim 19 under 35 U.S.C. §112, first paragraph, lack of written description, is withdrawn in view of Applicant's amendment.

The rejection of claims 1, 4-7, 13-17, 29, 33 and 35-39 under 35 U.S.C. §112, first paragraph, lack of written description, is withdrawn in view of Applicant's amendment.

The rejection of claims 1-16 under 35 U.S.C. §112, second paragraph, as being indefinite, has been withdrawn in view of Applicant's amendment.

5. Claims 1, 2, 5-16, 18-22, 29, 33-35 and 38 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 6, 8-16, 18-20, 23, 26, 28-36, 38-42, 44-46 and 51 of copending Application No. 09/332,275 for the reasons of record and as further discussed below.

Claims 1-24, 29 and 33-39 stand rejected under 35 U.S.C. §112, first paragraph, lack of enablement for the reasons of record and as further discussed below.

Claims 2, 3, 8-12, 18-22 and 34 stand rejected under 35 U.S.C. §112, first paragraph, lack of written description, for reasons of record and as further discussed below.

6. New grounds of rejection, necessitated by Applicant's amendment, are set forth below.

Response to Arguments

7. With regard to the provisional rejection of claims 1, 2, 5-16, 18-22, 29, 33-35 and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 6, 8-16, 18-20, 23, 26, 28-36, 38-42, 44-46 and 51 of copending Application No. 09/332,275, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant states that they agree to file a Terminal Disclaimer upon notice that the claims in the instant application and co-pending application 09/332,275 are allowable. In view of this, the rejection is maintained.

8. With regard to the rejection of claims 1-24, 29 and 33-39 under 35 U.S.C. §112, first paragraph, lack of enablement, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that 1) only one disease is recited in the claims (HIV) and that is it improper for the Examiner to require that the claimed invention be enabled for the entire field of gene therapy and for every disease mentioned in the specification because only one use for the expression vectors and methods of the invention is

required by law; 2) the Examiner has improperly directed the substance of the rejection to the in vivo gene therapy techniques and does not specifically address ex vivo gene therapy techniques; 3) that the Verma and others have reported success with ex vivo gene therapy; 4) that given the number of clinical trials underway, the Fox citation actuatlly suggests the overall safe and predictable nature of the procedure and that the scientific community considers these procedures to hold great promise of success; and 5) that the application contains a working example of ex vivo gene therapy by the incorporation of USP 5,399,346.

With regard to point 1), Applicant is reminded that the enablement must be commensurate in scope with the claimed invention. Only claim 39 is restricted to ex vivo gene therapy. The specification teaches both in vivo and ex vivo gene therapy approaches; thus it is entirely proper that enablement must be demonstrated for the full scope of the claims and therefore include both in vivo and ex vivo approaches. Furthermore, the claims are not restricted to HIV since only a subset of chemokine receptors (CXC4, CCR5, CCR1, CCR2b and CCR3) are known to mediate HIV infection. The specification does not teach any specific diseases associated with any other of the numerous other chemokine receptors (e.g. CXC1, CXC2, CXC3 and CXC5). As for the statement that the law requires only one use for the expression vectors and methods of the invention, this is applicable to a utility rejection under 35 USC §101, which Applicant is again reminded is not the basis for the pending rejection. With regard to point 2), while the well known obstacle of targeting efficiency and specificity may be ameliorated by an ex vivo approach, the problem of sustained gene

expression remains for ex vivo approaches. With regard to point 3), Verma's success in mice does not predict success in other mammals, such as humans, nor does it provide enablement for in vivo methods which are encompassed by the claims. With regard to point 4), while continued clinical trials may indicate overall safety (which is not in any case the issue with regard to enablement and is not the purview of the USPTO), it certainly does not indicate the "predictable nature" of gene therapy is success. Given the large number of clinical trials underway and the very, very few acknowledged therapeutic successes, indeed the prediction is that gene therapy will not work. Furthermore, the statement that the scientific community thinks these procedures hole great promise simply does translate into enablement. With regard to point 5), the Anderson patent has one example with a single patient. The heterologous gene is the human adenosine deaminase, which is an enzyme and thus catalytic in effect, which is not comparable to the pending claims. An enzyme may show therapeutic effect at a lower expression level than another molecule which requires a 1:1 stoichiometry (such as binding and retaining intracellularly every CCR5, for instance, expressed in a cell). Furthermore, the Anderson patent does not indicate actual therapeutic benefit. It is also noted with regard to claim 39 that this claim has been examined assuming that the expression vector is the patentable distinction in the claim. Therefore, Applicant's arguments are not persuasive individually or as a whole and the rejection is maintained.

9. With regard to the rejection of claims 2, 3, 8-12, 18-22 and 34 under 35 U.S.C. §112, first paragraph, lack of written description, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant has amended claims 1, 18, 29 and 35 to delete the use of the word "gene" however claims 2, 3, 8-12, 18 and 34 still recite "gene". Applicant does not provide any other argument. Therefore, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 8-12 rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "said chemokine gene" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "said chemokine gene" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "said chemokine gene" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "said chemokine gene" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "said chemokine gene" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

Claims 1-24, 29 and 33-39 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as

soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

January 13, 2003

JAMES KETTER
PRIMARY EXAMINER